

Date : 12/1/2021

TO WHOM IT MAY CONCERN

Sub: Detection of New SARS-CoV-2 Variant- Omicron (B.1.1.529) using the Clarity COVID19 Antigen Rapid Test Cassette.

In November 2021, a new SARS-CoV-2 variant (B.1.1.529) was identified in South Africa. Key mutations include 34 mutations on the spike protein of the virus, where 15 mutations occur in the RBD of the spike protein. Despite the significant mutation on the spike protein and its significant potential to influence this variant's immune escape and transmissibility, based on preliminary analysis, it is estimated that the **Clarity COVID-19 Antigen Rapid Test Cassette will still be able to detect the new variant.**

The Clarity COVID-19 Antigen Rapid Test is a qualitative, lateral flow immunoassay for the detection of the nucleocapsid protein of SARS-CoV-2. Comparing the mutations that occur on the nucleocapsid protein of the new variant Omicron (B.1.1.529) : P13L, E31del, R32del, S33del, R203K and G204R and the epitopes (the part of the antigen that binds to the antibody) of the antibodies used on the test, it was determined that all 6 mutations are outside the epitopes of the antibodies used in the test. This indicates that the binding of the antibodies and the antigen will likely not be affected, **therefore, the risk of the new variant not being detected by the Clarity COVID-19 Antigen Rapid Test is low.**

As standard reference materials become available, Salofa Oy and Clarity will conduct wet-testing to confirm the ability of the test to detect the new SARS-CoV-2 variant (B1.1.529).

We hereby certify that the above statements are true and correct.

A handwritten signature in black ink, appearing to read "Ashish Parikh".

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Clear Vision - Clear Results

Clarity Brand Rapid Diagnostics

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